



Af/3732\*

TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No.  
MED-02702/29

Application Of: Masini

Serial No.  
09/523,503

Filing Date  
March 10, 2000

Examiner  
E. Robert

Group Art. Unit  
3732

Invention: **OPTIMIZING PATELLAR FEMORAL MECHANICS THROUGH ALTERNATIVE DEPTH  
REFERENCING**

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:  
July 17, 2003

Applicant is a small entity under 37 CFR 1.9 and 1.27.

A verified statement of small entity status under 37 CFR 1.27:

- ☐ is enclosed.  
☐ has already been filed in this application.

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Signature

Dated: Sept. 17, 2003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of: Masini

Serial No.: 09/523,503

Group No.: 3732

Filed: March 10, 2000

Examiner: E. Robert

For: OPTIMIZING PATELLAR FEMORAL MECHANICS THROUGH ALTERNATIVE DEPTH  
REFERENCING

**APPELLANT'S BRIEF UNDER 37 CFR §1.192**

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Dear Sir:

**I. Real Party in Interest**

The real party and interest in this case is MedIdea, LLC, a Michigan limited liability corporation,  
by assignment.

**II. Related Appeals and Interferences**

There are no appeals or interferences which will directly affect or be directly affected by or have  
a bearing on the Board's decision in the pending appeal.

**III. Status of Claims**

The present application was filed with 15 claims. Claim 16 was added in January 2001. Claims  
1-7 have been withdrawn from consideration. Accordingly, claims 8-16 are pending in this application,  
and are under appeal.

**IV. Status of Amendments Filed Subsequent to Final Rejection**

No after-final amendments have been filed.

**V. Concise Summary of the Invention**

In conjunction with knee-replacement surgery, the present invention allows for the creation of a symmetric extension gap while providing restoration of the joint line with respect to the patellar femoral joint in the distal plane, thereby optimizing patellar femoral mechanics. (Specification, page 4, lines 16-20). In the preferred embodiment, this is achieved by referencing the extent of the lateral femoral condyle or trochlear region, and resecting the distal femur in accordance with the extent of the lateral femoral condyle or trochlear region (Specification, page 4, line 2 to page 5, line 1). As an alternative, the invention provides for distal femoral and proximal tibial components having bone-contacting and articulating surfaces which account for the measured extent of the lateral femoral condyle or trochlear region (Specification, page 5, lines 1-4).

A method of preparing a distal femur according to the invention includes the steps of installing a rod or stem within the intramedullary canal, and attaching a referencing fixture thereto. The extent of the lateral femoral condyle or trochlear region is measured using the referencing fixture, and the distal femur is resected in accordance with the extent of the lateral femoral condyle or trochlear region (Specification, page 5, lines 5-9). The method typically further includes the step of placing a spacer between the referencing fixture and the lateral femoral condyle or trochlear region (Specification, page 5, lines 9-11). The embodiment of the invention involving the use of modified components proceeds similarly, except that after measuring the extent of the lateral femoral condyle or trochlear region using the referencing fixture, distal femoral and proximal tibial components are implanted having bone-contacting and articulating surfaces which take the measurement into account (Specification, page 5, lines 11-15).

**VI. Concise Statement of Issues Presented For Review**

1. Were claims 12-15 properly rejected under 35 U.S.C. §101 as being drawn to non-statutory subject matter?
2. Were claims 12-16 properly rejected under 35 U.S.C. §112, second paragraph as being indefinite?

3. Are claims 8-13, 15 and 16 anticipated under 35 U.S.C. §102(b) by Whiteside, U.S. Patent No. 4,474,177?

4. Are claims 8-13 and 16 anticipated under 35 U.S.C. §102(b) by White, U.S. Patent No. 5,662,656?

## VII. Grouping of Claims for Each Ground of Rejection Which Appellant Contends

Appellant states that all of the rejected claims stand or fall with claim 8.

## VIII. Argument

### A. The Rejections Under 35 U.S.C. §101 and §112, Second Paragraph.

As a preliminary matter, Appellant argues that the rejections under 35 U.S.C. §101 and §112, second paragraph, are improper. In the alternative, if the Board feels these rejections have merit, Appellant respectfully requests a remand with guidance.

Regarding the rejection under 35 U.S.C. §101, claim 14 sets forth a fixture including a movable member which references *one of a* non-prominent condyle or trochlear region, and a cutting guide to resect *a femur* in accordance with the reference made using the fixture (emphasis added). Thus, as argued of record, Appellant contends that human body parts are only being referred to and are not being positively recited.

As to the rejection under 35 U.S.C. §112, the Examiner object to Appellant's use of "moveable member." However, this faithfully describes the component in question and is not inconsistent with the disclosure or specification. Appellant knows of no rule that the exact language from the specification must be used in a claim so long as indefiniteness is avoided.

### B. The Rejections Under 35 U.S.C. §102(b).

Claim 8 stands rejected under 35 U.S.C. §102(b) over Whiteside, U.S. Patent No. 4,474,177 and under 35 U.S.C. §102(b) by White, U.S. Patent No. 5,662,656. These two references will first be succinctly reviewed, followed by Appellants arguments on the merits.

Whiteside ('177) resides in a method and apparatus for preparing the distal surface of a femur to receive a distal femoral prosthesis. The system involves an intramedullary reamer which is used to internally locate the central long axis of the femur, an intramedullary alignment guide which is inserted into the space left in the intramedullary canal upon removal of the reamer and at least one femoral surface modifying instrument which cooperatively engages with a guide handle attached to the intramedullary alignment guide to accomplish the shaping of the distal femoral surface. The intramedullary alignment guide has a rod portion extending into the femoral intramedullary canal whose central long axis corresponds with the central long axis of the femur. The guide handle is attached to that rod portion at a preselected angle such that the shaping instruments fixed thereto assume the proper alignment with respect to the central long axis of the femur such that the distal femoral surface is shaped relative to that axis in a simple and accurate manner.

The Examiner suggests that "Whiteside ... discloses ... installing the fixture onto a distal femur which references i.e., refers to or indicate [sic], the non-prominent condyle or trochlear region (referring to Figure 20), and resecting the femur in accordance with a reference or indication made by the fixture."

However, Whiteside simply states, at column 9, lines 53-55 that:

"The cutting guide surface 83 (not shown) is in position to remove the desired amount of bone (approximately the thickness of the distal portion of the femoral prosthesis component)."

Accordingly, Whiteside is entirely silent with regard to referencing *any* feature of the distal femur, regardless of whether such features include condyles or trochlear region. In addition, if Whiteside were to reference the non-prominent condyle or trochlear region, more bone would be removed from the most prominent condyle than the thickness of the prosthesis to be inserted, which is contrary to the statements just cited. Anticipation may be established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. RCA Corp. v. Applied Digital Data Systems, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). Moreover, anticipation requires the presence of all elements of a claimed invention as arranged in the claim, such that a disclosure "that 'almost' meets that standard does not 'anticipate'." Connell v. Sears, Roebuck Co., 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). In this case, the Whiteside patent does not meet the standard.

Claims 8 also stands rejected under 35 U.S.C. §102(b) over White ('656). White is direct to

instrumentation and a method of sizing and resecting the distal femur. The instrument body construct has a distal aspect abutting surface with a planar face for abutting the distal aspect of a distal femur at a fixed angle to the longitudinal axis of the distal femur, having a posterior aspect abutting surface with a planar face for abutting the posterior aspect of the distal femur, and having a passageway therethrough. An anterior feeler gauge is provided for attachment to the instrument body construct and for contacting a portion of the anterior aspect of the distal femur to indicate the anterior-to-posterior size of the distal femur. A resection guide is provided for attachment to the instrument body construct for guiding a bone resection tool to resect the distal femur. The resection guide may have a first position for guiding the bone resection tool to perform an anterior femoral resection and a second position for guiding the bone resection tool to perform a distal femoral resection.

Although the White patent does disclose a reference guide 91, this is used to measure the anterior-posterior thickness of the distal femur to determine the cuts for a particular size implant, and has nothing to do with measuring the distal extent of either condyle or the trochlear region. Reference is made to Figure 11 of White, for example, which clearly shows the way in which the reference guide 91 is used on the anterior side of the bone. In addition, reference is made to column 9, lines 34-39, where it is explained that:

“... valgus module 61, 63, 65 [is] moved proximally until the planar face portion 30 of the distal aspect of butting surface 29 abuts the distal aspect 19 the distal femur 13.”

Accordingly, such a structure cannot possibly contact either the non-prominent condyle or trochlear region. Again, since anticipation may be established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention, the White patent falls short of anticipation..

### Conclusion

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellant seeks the Board's concurrence at this time.

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Date: Sept. 17, 2003

Respectfully submitted,

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APPENDIXCLAIMS ON APPEAL

8. A method of resecting a distal femur having prominent and non-prominent condyles separated by a trochlear region, the method comprising the steps of:

- a) installing a fixture onto the distal femur which references the non-prominent condyle or trochlear region; and
- b) resecting the femur in accordance with the reference made in (a).

9. The method of claim 8, wherein the step of installing a fixture onto the distal femur includes the step of:

placing an intramedullary rod in the distal femur having a movable guide; and  
moving the guide until the guide touches the non-prominent condyle or trochlear region.

10. The method of claim 8, wherein:  
the femur has a longitudinal axis; and  
the resection is substantially transverse to the longitudinal axis.

11. The method of claim 8, wherein the resection is a distal cut.

12. Apparatus for resecting a distal femur having prominent and non-prominent condyles separated by a trochlear region, comprising:

- a fixture including a movable member which references one of a non-prominent condyle or trochlear region; and
- a cutting guide to resect a femur in accordance with the reference made using the fixture.

13. The apparatus of claim 12, wherein the fixture further includes:  
an intramedullary rod; and  
wherein the member is movable on the rod.



15. The apparatus of claim 12, further including a prosthesis installable on the distal femur in accordance with the resection made with the cutting guide.

16. The apparatus of claim 12, wherein the cutting guide is movable relative to the member.